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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,449	09/21/2001	Troy Holland	BioCure 161	5786

27029 7590 08/19/2003

BIOCURE, INC.
2975 GATEWAY DRIVE
SUITE 100
NORCROSS, GA 30071

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,449

Applicant(s)

HOLLAND ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-11, 13-17, 21-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-11, 13-17, 21-23, 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment A, both filed 06/16/2003.

Claims 5-7, 12, 18-20, 24 and 26 have been canceled. Claims 1-4, 8-11, 13-17, 21-23, and 25 are included in the prosecution.

The Standing Rejections:

1. Claims 1-4, 8-11, 13-17, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '862 in view of US '061.

US '862 disclosed method and composition for forming *in situ* tissue adherent barrier using sprayer to apply cross-linkable component to the tissue (abstract). When the sprayer is activated, the emergent spray contacts tissue, resulting in mixing and cross-linking of the components to form coating, e.g. hydrogel, on the tissue surface (col.2, lines 5-9). The components are in the form of solution and comprise water-soluble, crosslinkable, biodegradable macromers (col.2, lines 19-34; col.7, lines 24-30). The composition comprises bioactive drugs (col.3, lines 35-36). The hydrogel is formed by gelation or precipitation of the polymeric solution and initiated by redox (col.4, lines 24-27; col.6, lines 3-5). The claimed composition is anticipated by US '862.

The reference does not teach PVA macromer in particular, NO as an active agent, or debriding the wound when the dressing is removed.

It is within the skill in the art to determine the biologically active agent to be included in the wound dressing according to particular need. No criticality has been established in using NO in the composition of the wound dressing. The references teach the sprayable composition as an adhesive, thus it will debride the wound upon its removal.

US '016 teaches a hydrogel of biodegradable, polymerizable, crosslinkable, water soluble macromers used for protection of the tissue surfaces, i.e. dressing (abstract; col.4, lines 29-31). The macromers form hydrogel *in situ* when applied to the tissue (col.5, lines 65-68; col.6, lines 16-17). The macromers comprise PVA and antibiotics (col.8, line 42; col.10, lines 29-35).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a wound dressing formed *in situ* by spraying a formulation comprising water soluble crosslinkable macromers as taught by US '862 and select PVA as a macromer as disclosed by US '016, motivated by the teaching of US '016 that the hydrogel comprising macromers such as PVA can be administered during surgery and out-patient procedures and polymerized as tissue adhesive or drug delivery of anti-angiogenic agents, with reasonable expectation of success of the delivered dressing in treating wounds and debriding the underlying tissue when needed.

Response to Arguments

2. Applicant's arguments filed 06/16/2003 have been fully considered but they are not persuasive.

Applicants traverse the rejection of claims 1-4, 8-11, 13-17, 21-23, and 25 as being unpatentable over US '862 in view of US '016 by arguing that the cited references do not teach or suggest water soluble PVA macromers having one or more pendant crosslinkable groups.

In response to the above argument, it is the examiner position is that the references in combination teach the hydrogel wound dressing comprising PVA that forms hydrogel *in situ*. The primary reference teaches the genus of water-soluble crosslinkable macromers, and it is *prima facie* obvious to replace the genus by a species that disclosed by the secondary reference to perform the same function.


3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY INVENT EXAMINER
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